5. 510(k) Summary

MERIDIAN MEDICAL

1303 Avocado Avenue, Suite 265
Newport Beach, CA 92660

APR - 2 2007

Submitter's name:	Meridian Medical
Address:	1303 Avocado Ave., Suite 265 Newport Beach, CA 92660
Phone:	949-718-9220
Fax number:	949-718-9234
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821 grace@regulatoryspecialists.com

Date the summary was prepared: December 29, 2006

Name of the device:	Blue Shark
Trade or proprietary name:	Blue Shark
Common or usual name:	External fixation system
Classification name:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component (per 21 CFR section 888.3030)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

K#	Device Name	Applicant
K032427	FEP	Meridian Medical
K011697	EBI XFIX ACCESS PELVIC FIXATOR	EBI, L.P.

Description of the device:

The pelvic external fixators are composed of four different elements composing the frame of the fixator connected by screws and rings. The fixator is assembled on four steel screws that are implanted into the pelvis on the iliac crest depending on the selected implantation.

Intended use of the device:

> The Blue Shark is an external fixation device indicated for the rigid stabilization of complex fractures of the pelvic girdle. This external fixation device can be utilized for Type B and Type C fractures.

Summary of the technological characteristics of our device compared to the predicate device:

It has been shown that the Meridian Medical Blue Shark and the Predicates, FEP and EBI XFIX ACCESS PELVIC FIXATOR devices have similar technological characteristics, similar design and materials and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meridian Medical
% Ms. Grace Holland
Regulatory Specialists, Inc.
3722 Sausalito Avenue
Irvine, California 92606

APR - 2 2007

Re: K070016
Trade/Device Name: Blue Shark
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: December 29, 2006
Received: January 3, 2007

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K070016

Device Name: Blue Shark

Indications for Use:

The Blue Shark is an external fixation device indicated for the rigid stabilization of complex fractures of the pelvic girdle. This external fixation device can be utilized for Type B and Type C fractures

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Millerm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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